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THE BOC GROUP

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**Subject:** 510(k) Summary of Safety and Effectiveness Information  
for the Ohmeda 7900 Anesthesia Ventilator.  
**Proprietary:** Ohmeda 7900 Anesthesia Ventilator  
**Common:** Continuous Ventilator  
**Classification:** Ventilator, Continuous Class II - 21CFR868.5895 - 73CBK

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

The Ohmeda 7900 Anesthesia Ventilator is substantially equivalent to the currently marketed Ohmeda 7800 Anesthesia Ventilator.

The Ohmeda 7900 Anesthesia Ventilator provides mechanical ventilation for patients during surgery, as well as adjustment and monitoring various patient parameters-

Patient breathing waveform during volume mode or pressure mode  
 $V_E$  Exhaled minute volume  
 $V_{TE}$  Exhaled tidal volume  
 $O_2$  Percent of oxygen inspired  
f/min Units of breath rate per minute  
 $P_{max}$  Maximum airway pressure during a patient breath  
 $P_{mean}$  Mean airway pressure, calculated every patient breath or 10 seconds whichever occurs first  
 $P_{plateau}$  Airway pressure measured at the end of inspiratory pause time.

The 7900 Anesthesia Ventilator is a microprocessor based, electronically controlled, pneumatically driven ventilator with a built in monitoring system for inspired oxygen, airway pressure and exhaled volume. Sensors in the breathing circuit are used to control and monitor patient ventilation as well as measure inspired oxygen concentration. This allows for compensation of compression losses, fresh gas contribution, and small leakage in the breathing absorber, bellows and system. User settings and microprocessor calculations control breathing patterns. User interface keeps settings in memory. The user may change settings with a simple and secure setting sequence. A bellows contains breathing gasses to be delivered to the patient. Positive End Expiratory Pressure (PEEP) is regulated electronically. Positive pressure is maintained in the breathing system so that any leakage that occurs is outward. An RS-232 serial digital communications port connects to and communicates with external devices.

The software for the Ohmeda 7900 Anesthesia Ventilator has been developed following a rigorous software development process and has been fully specified and validated by Ohmeda.

The Ohmeda 7900 Anesthesia Ventilator complies with the following standards:

1. ASTM F1101 - Sections 5.2, 5.3.2, 5.4.3, 5.5, 5.7.1, 6.2.2, 6.2.3, 6.6 and 6.8.1
2. ISO 10651 - Sections 50.3.1, 51.10 and 51.7
3. IEC 601-1 - 1988, EN 60601-1
4. IEC 601-1-2, EN 60601-1-2
  - CISPR 11 Group 1 (EN55011)
  - EN 55011: "Limits and Methods of Measurement of Radio Interference Characteristics of Industrial, Scientific and Medical (ISM) Equipment"
  - IEC 801-2, 8kV air, 3kV contact
  - IEC 801-3, 3V/m
  - IEC 801-4, 2kV power line
  - IEC 801-5, 2kV line to earth, 1 kV line to line
5. EN 60601-1-4
6. DIN 13252/06 - 1984
7. E-DIN 132252/01 - 1991
8. prEN 740/12 - 1994
9. UL 2601 - 1994
10. IEC 68-2-3 Test Ca, IEC 68-2-1 Test Ab-Cold, IEC 68-2-2 Test Bb-Hot, IEC 68-2-14, IEC 68-2-34, IEC 68-2-6, IEC 68-2-27

The Ohmeda 7800 Anesthesia Ventilator and the Ohmeda 7900 Anesthesia Ventilator are substantially equivalent in technological characteristics, theory of operation and measurement methods. The Ohmeda 7900 Anesthesia Ventilator is the next generation of ventilator, utilizing the technological advances of today to bring Ohmeda ventilators to the next century.

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